



## PRESS RELEASE

---

### Safety of ROCKSTAR Energy Drinks

In response to recent publicity surrounding energy drinks, Rockstar, Inc. (manufacturer of Rockstar energy drink products), would like to report that an independent panel of scientists, qualified by relevant national and international experience and scientific training in food safety, has reviewed the key ingredients of Rockstar energy drink products and their use levels. The Expert Panel has concluded that the intended use of the key ingredients in Rockstar products is safe and meets the "Generally Recognized As Safe" GRAS standard. The Expert Panel evaluation was provided under the guidance of Dr. John Doull (M.D., Ph.D.), while the GRAS process was conducted by Dr. Ashley Roberts (Ph.D.) of Intertek Cantox. Intertek Cantox is a global leader in providing regulatory, scientific, and toxicology consulting services specific to the areas of food safety and nutrition. For over 25 years, Intertek Cantox experts have successfully resolved complex scientific issues, developed effective regulatory compliance plans, and facilitated global regulatory approvals for new products.

The safety of Rockstar energy drink products is supported on the basis that:

1. The total amount of caffeine content from all sources (either 80 mg or 120 mg of caffeine per 8 ounce serving, depending on product), which is listed on the label of all Rockstar energy drink products, is less than that of the following premium coffees:
  - a. Starbucks® "Pike Place® Roast" (standard house blend) 16 ounce Grande coffee contains 330 mg of caffeine. *(source: Starbucks® website - web link here)*
  - b. Starbucks® "Pike Place® Roast" (standard house blend) 20 ounce Venti coffee contains 415 mg of caffeine. *(source: Starbucks® website - web link here)*
2. Rockstar fulfills all requirements stipulated by the FDA to sell products labelled as either Conventional Foods or as Dietary Supplements.
3. Rockstar energy drink products indicate the total amount of caffeine from all sources on all product labels.
4. Rockstar energy drink products list the following statement on all product labels:  
***"Not recommended for children, pregnant or nursing women, or those sensitive to caffeine."***





## PRESS RELEASE

5. The Expert Panel critically evaluated the intended conditions of use - including use levels and estimated dietary intakes - of caffeine, taurine, L-carnitine, inositol, guarana extract, milk thistle, and ginseng extract in all Rockstar energy drink products. The Expert Panel applied the requisite safety standard, *i.e.*, there must be a reasonable certainty of no harm under the conditions of intended use of the substance. The Expert Panel unanimously concluded that such use of caffeine and all other ingredients in Rockstar products is safe and GRAS based on scientific procedures.
6. Taurine occurs naturally in the diet as a component of meat and poultry, seafood, and dairy products. It also is present in breast milk and some infant formulas. The presence of taurine in cow's milk based infant formula is attributed to its natural occurrence in the milk, whereas taurine is added to infant formula formulated from soy protein.
7. Guarana is a natural source of caffeine; the caffeine content derived from the Guarana used in Rockstar energy drink products is less than one milligram per 8 ounce serving. The caffeine content from Guarana is included in the calculation of total caffeine from all sources as listed on all Rockstar product labels.
8. In evaluating these ingredients, the Expert Panel considered the potential for synergistic effects of the ingredients as well as any known adverse health effects.
9. Claims that the American Academy of Pediatrics recommends no more than 100 mg caffeine per day for adolescents are inaccurate. Neither Rockstar nor the U.S. FDA has been able to verify this purported recommendation.
10. Furthermore, in another letter dated November 21, 2012 (U.S. FDA, 2012c) the U.S. FDA stated that it has "searched the literature but did not find any information that calls into question the safety" of taurine, an amino acid, or guarana, an herb as currently used in beverages.

Energy drinks containing caffeine are popular drinks available for purchase at most supermarkets, box stores, grocery stores, convenience stores and gas stations nationally with current annual category sales estimated to be approximately 4.4 billion units in the United States (Rockstar personal communication). Since brand inception in 2001, Rockstar has produced over 3 billion cans of Rockstar energy drink products for the U.S. market. Rockstar energy drink products in the U.S. contain either 80 mg or 120 mg of caffeine per 8 ounce serving, depending on the product.

The FDA posted a summary of adverse effect reports (AER) obtained via the Center for Food Safety and Applied Nutrition Adverse Event Reporting System (CAERS) through October 2012 that related to products marketed as energy drinks or energy shots which included the brands Red Bull,







## PRESS RELEASE

5 Hour Energy, Monster, and Rockstar (U.S. FDA, 2012a). The reports were received under this post-surveillance system between January 1, 2004 and October 23, 2012. It is important to note that these reports cannot determine cause and effect, as is stated by the FDA in the summary: *"the adverse effect report itself about a particular product only reflects information AS REPORTED [FDA's emphasis] and does not represent any conclusion by FDA regarding a causal relationship or association with the product or ingredient."*

The summary of CAERS reports released by the FDA included only 13 reports of adverse effects from Rockstar energy drink products (including zero deaths) for the time frame 2006 through October 2012. The lethal dose of caffeine in an average person weighing 150 pounds (68 kg) is approximately 10,000 mg, which is equivalent to the consumption of 82 cans of 8 ounce Rockstar energy drink, or 656 ounces of liquid. This volume is 10 times greater than the total amount of fluid that is typically consumed in a full day and it is therefore physically impossible to consume this much liquid in one sitting. It is also important to note that of the 13 CAERS reports received regarding Rockstar energy drink products over the 7 year time frame, 6 of those 13 CAERS reports received allegedly claimed either product spoilage or object in can.

Compared to the more than 2 billion cans of Rockstar products sold in the U.S. since 2006 (with over 3 billion sold since brand inception in 2001), the 13 CAERS reports received between 2006 and October 2012 (and it should be noted that these are only recorded in the AER system, and represent no defined relationship or proof of association with Rockstar products or its ingredients) represent a very small fraction (0.00000065%) of the overall number of Rockstar energy drink units produced since 2006. The SAMHSA Drug Abuse Warning Network has issued an update to a report released in 2011 (SAMHSA, 2011, 2013) on hospital visits involving energy drinks (along with alcohol and/or illegal or legal drug abuse or intake) but did not specify how many involved Rockstar products, or the quantity of energy drinks consumed, or the specific level of caffeine intake. The 2011 report indicated that greater than 50% of patients aged 18 to 25 admitted to combining drug or alcohol use with the energy drinks, while the latest report indicated that 42% of all visits across the age groups also involved pharmaceutical, drug or alcohol consumption. With these confounding factors it cannot be determined from the information provided what role, if any, energy drinks contributed to the visit and/or the symptoms. Furthermore, given that it was a self-reporting system, it cannot be determined if those subjects visiting the emergency department, particularly younger patients, disclosed all other concomitant drug or alcohol use. Thus, drug use is likely to have been a much higher percentage than disclosed.

Numerous multi-ingredient foods and beverages contain caffeine including coffee, tea, chocolate, soft drinks, and ice cream, which all have a long history of safe consumption in the U.S. and global diet, and are targeted towards all age groups. Regulating food products on the basis of caffeine content and consumption levels would therefore impact many different product categories, not just energy drinks. Following a comprehensive evaluation of the literature for caffeine, a panel of





## PRESS RELEASE

independent scientists, qualified by scientific training and relevant national and international experience to evaluate the safety of food ingredients, was convened to evaluate the conditions of use of caffeine in Rockstar energy drink products. The Expert Panel unanimously concluded that the intended use of caffeine, produced in accordance with current good manufacturing practice and meeting applicable *Food Chemical Codex specification*, in Rockstar energy drink beverages at levels up to 120 mg per 8 ounce serving is safe. The Expert Panel unanimously confirmed that the intended use of caffeine in Rockstar energy drink products is GRAS based on scientific procedures. The Expert Panel also noted that, in their unanimous opinion, other qualified experts would concur with these conclusions. The amount of caffeine in Rockstar energy drink products per 8 ounce serving (either 80 mg or 120 mg depending on product) is considerably less than that of an 8 ounce serving of Starbucks® Pike Place Roast® coffee at 160 mg of caffeine, while the 20 ounce Starbucks® Pike Place Roast® coffee contains 415 mg of caffeine. Ben and Jerry's® Coffee Heath Bar Crunch contains 84 mg of caffeine per 8 ounce serving.

Some media reports and health group websites have stated that the American Academy of Pediatrics (AAP) recommends that adolescents should not consume more than 100 mg of caffeine per day. However, following a thorough search of the literature a detailed reference for this statement could not be found in these reports.

In the FDA letter dated November 21, 2012 (U.S. FDA, 2012c), it is stated that the FDA contacted the AAP and reviewed their website but was not able to get verification that the AAP has a policy statement supporting an upper limit of 100 mg caffeine per day for adolescents. An independent search of the AAP website also did not identify any such policy statement. Thus, it is incorrect to state that the maximum safe amount of caffeine for adolescents is 100 mg per day.

In a letter dated August 10, 2012 concerning caffeine, the FDA stated that, while the Agency is reviewing recently published safety studies on caffeine, "the available studies do not indicate any new, previously unknown risks associated with caffeine consumption" (U.S. FDA, 2012b). Furthermore, in another letter dated November 21, 2012 (U.S. FDA, 2012c) the U.S. FDA stated that it has "searched the literature but did not find any information that calls into question the safety" of taurine, an amino acid, or guarana, an herb as currently used in energy drink products.

Given the above, there is no expectation that consumption of Rockstar energy drinks containing 80 mg or 120 mg caffeine per 8 ounce serving, in adherence with the product label, should be associated with adverse health effects. The Expert Panel convened to evaluate the safety of caffeine also assessed ginseng extract, guarana extract, L-carnitine, milk thistle extract, and taurine, and concluded unanimously that the use of these ingredients in Rockstar energy drink products are safe. The Expert Panel also found such uses to be GRAS based on scientific procedures. Estimates of dietary intakes of these non-caffeine ingredients from consumption of Rockstar energy drink products were determined to be well below estimates of consumption from





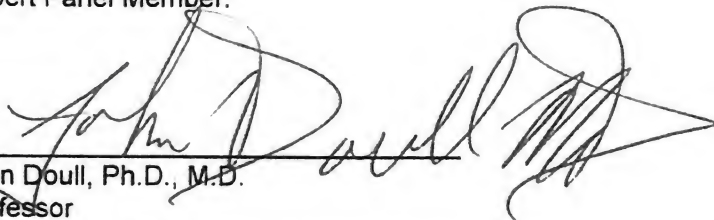


## PRESS RELEASE

other food sources and/or orders of magnitude below no adverse effect levels determined from safety studies. As all ingredients are present in amounts that are GRAS and/or are found in various foods in comparable amounts, there is no expected safety concern associated with these ingredients alone, or in combination, from consumption of Rockstar energy drink products.

For further information please contact [INFO@ROCKSTARENERGY.COM](mailto:INFO@ROCKSTARENERGY.COM)

Expert Panel Member:



John Doull, Ph.D., M.D.  
Professor  
Department of Pharmacology  
The University of Kansas Medical Center

